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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,617	11/04/2005	Rachel Mary Haywood	70027880-0010	1759

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SONNENSCHEIN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,617	HAYWOOD ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *9-11,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-18 are pending in this application. Addition of new claim 18 is acknowledged.

2. Claims 9-11, 13, and 14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/22/08.

3. Claims 1-8, 12, and 15-18 are examined.

Claim Objections

4. The objection to claim 12 is withdrawn in view of Applicant's amendment to claim 12.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-8, 12, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurkiewicz et al ("EPR Detection of Free Radicals in UV-Irradiated Skin: Mouse *Versus* Human", *Photochemistry and Photobiology*, 1996, 64(6): 918-922) in view of Robinson (US Patent 5,968,485).

The claimed invention is drawn to a method for measuring the effectiveness of a sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation, the method comprising irradiating a sample of human skin or of an effective substitute therefor (herein: "skin"), shielded with the sunscreen composition or other skin preparation to be tested, with UV radiation comprising UVA wavelengths, and determining by electron spin resonance (ESR) spectroscopy the level of induced production of ascorbate radical in the shielded skin; and determining a quantitative measure of the effectiveness of the sunscreen composition in reducing the exposure of human skin to UVA radiation by comparison of the said level of acerbate radical production in the shielded skin with the level of ascorbate radical production induced in reference skin under substantially quantitatively comparable conditions (see claims 1, 15, and 18).

Jurkiewicz et al. teach EPR (i.e., ESR) detection of ascorbate free radicals in UV-irradiated skin (see abstract). A sample of human skin was irradiated with UV radiation comprising UVA wavelengths, either unshielded or shielded with a shield such as a filter (see page 919, third full paragraph), and the ascorbate radical EPR signal was determined. Jurkiewicz et al. also teach irradiating a sample to which the photoprotective agent Desferal has been topically applied, and with which a 305 nm UV cutoff filter was used (page 921, first paragraph).

Jurkiewicz et al. do not teach the use of a photoprotective (i.e., sunscreen) agent in the UVA range (320 - 400 nm), and do not specifically state that a quantitative measure of the effectiveness of the sunscreen composition was determined.

Robinson teaches UVA-absorbing dibenzoylmethane sunscreen actives which absorb UV radiation having a wavelength of from about 320 nm to about 400 nm (col. 3, lines 50-55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select a sunscreen active in the UVA region (e.g., the sunscreen active taught by Robinson) to be used on the shielded skin. One skilled in the art would have been motivated to do so because the process of Jurkiewicz et al. is taught to be used on unshielded skin in both the UVA and UVB ranges, and because the process is also taught to be used on shielded skin (e.g., when Desferal is topically applied). Therefore, it naturally follows that one skilled in the art would also use the process taught by Jurkiewicz et al. for measuring the effectiveness of a sunscreen active in the UVA region, such as the sunscreen active taught by Robinson.

Regarding the step of determining a quantitative measure of the effectiveness of the sunscreen composition in reducing the exposure of human skin to UVA radiation (claims 1 and 16), it would have been obvious to a person having ordinary skill in the art at the time the invention was made to compare levels of ascorbate radical production in the shielded and reference skin samples. Comparing the data obtained between a sample and its comparable reference is generally conventional and well within the capacity of one of ordinary skill in the art (as substantiated by Applicant's remarks on page 14 of the specification), and does not impart patentability to the claims.

Regarding claims 2 and 3, Jurkiewicz et al. teach that the skin sample may be irradiated in the absence of a photoprotective agent (i.e., sunscreen composition or

other skin preparation). The steps of measuring a reference using conditions (such as UV radiation and ESR conditions) comparable to those used with the test sample, are conventional steps followed when comparing a test sample to a reference sample, and well within the capacity of one of ordinary skill in the art.

Regarding claims 4 and 5, Jurkiewicz et al are silent with respect to whether or not the test and reference skin samples are the same. However, one skilled in the art of EPR spectroscopy would be able to control the dose of UVA radiation within the parameters of routine experimentation, such that the skin samples could be used once (wherein the test and reference skin samples are different but functionally comparable), or more than once (wherein the test and reference skin sample are the same).

Regarding claims 6 and 7, Jurkiewicz et al teach the UV-induced production of other radicals when the skin samples are irradiated in the presence of a spin trap molecule (page 920).

Regarding claims 8 and 17, the ranges disclosed for UV radiation and UVA radiation are the standard accepted wavelength ranges for UV and UVA radiation, and well within the capacity of one skilled in the art. For example, Robinson teaches that the UVA-absorbing sunscreen active absorbs UV radiation having a wavelength of from about 320 nm to about 400 nm (col. 3, lines 52-55).

Regarding claim 12, the method of claim 1 is found obvious for reasons stated above, and the expression of said effectiveness is merely a mathematical manipulation of data obtained by said method, and does not impart patentability to the claim.

Response to Arguments

7. Applicant's arguments filed 9/23/08 have been fully considered but they are not persuasive.

Applicants first argue that Jurkiewicz does not teach irradiating shielded skin, citing that the filters described at page 919 of Jurkiewicz do not shield the skin from UVA radiation as is claimed in the instant application (noting paragraphs 4 and 5 of the declaration filed with the response). Applicants also argue that the Desferal experiment of Jurkiewicz deliberately failed to shield the Desferal-coated skin sample from UVA to see what the result would be as a means for studying the interaction of an iron chelator with skin heme iron (noting paragraphs 7 and 8 of the declaration filed with the response).

This argument is not persuasive because Jurkiewicz teaches that the topical application of Desferal significantly reduced UV-induced free radical formation, and after exposure to UV radiation Desferal reduced the radical signal (page 921, column 1, lines 4-20), and therefore reasonably reads on the limitation of irradiating a sample of human skin shielded with the skin preparation to be tested, as recited in claim 1. That it was determined that Desferal acts not as a UV blocking agent but rather by an iron sequestration mechanism does not teach away from the claimed invention, but is merely a statement regarding its effectiveness, and therefore also reads on the claimed invention.

Applicants also argue that the Robinson and Jurkiewicz references are improperly combined because Jurkiewicz discloses the antithesis of shielding skin from UVA, as the entire purpose of Jurkiewicz was to expose unshielded skin to UVA. Applicants conclude that a person of ordinary skill in the art would not be motivated to substitute either the filters or the photoprotective agent (Desferal) of Jurkiewicz with the sunscreen of Robinson, as doing so would negate Jurkiewicz's purpose to expose unshielded skin to UVA.

This argument is not persuasive because Jurkiewicz clearly teaches the application of Desferal, which it labels as a "photoprotective" agent (page 921). The effect of the topical application of Desferal to skin was the decrease in radical production, which is an indicator of oxidative events. The skin to which Desferal was applied was exposed to UV radiation, which would include UVA wavelengths (see page 921 and 919). One skilled in the art, having observed decreased radical production from one photoprotective agent, would therefore be motivated to test other photoprotective agents, such as the photoprotective agent taught by Robinson, based on their functional equivalency as photoprotective agents.

Applicants also argue that Jurkiewicz does not disclose, teach, or suggest determining a quantitative measure of the effectiveness of sunscreen in the manner claimed in the instant application, nor that there is a quantitative reduction in ascorbate radical signal intensity in proportion with the reduction in radiation exposure, nor that ESR spectra from more than one skin sample be compared quantitatively (noting paragraphs 10 and 11 of the declaration filed with the response). Applicants further

argue that relevant portions of the specification merely teach that providing the apparatus, once one has been taught the invention, is within the capacity of a person of ordinary skill in the art.

This argument is not persuasive because the steps of measuring a reference using conditions (such as UV radiation and ESR conditions) comparable to those used with the test sample, are conventional steps followed when comparing a test sample to a reference sample, and well within the capacity of one of ordinary skill in the art.

Conclusion

No claims are allowed at this time.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611